Citation:

Sichieri R, Moura AS, Genelhu V, Hu F, Willett WC. An 18-mo randomized trial of a low-glycemic-index diet and weight change in Brazilian women. *Am J Clin Nutr*. 2007 Sep; 86(3): 707-713.

PubMed ID: 17823436

Study Design:

Prospective Cohort Study

Class:

A - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

NEUTRAL: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To investigate the effect of a larger difference in glycemic index of two diets (all other dietary components held equal) on weight and satiety in healthy young, overweight Brazilian women.

Inclusion Criteria:

Healthy women:

- Body mass index (BMI) of 23 to 29.9kg/m^2
- Aged 25 to 45 years
- Not pregnant or breastfeeding
- Had at least one child
- Did not anticipate a pregnancy in the next year.

Exclusion Criteria:

Women:

- With a physician-diagnosed thyroid disease or diabetes
- Who were menopausal
- Who could not eat beans on a daily basis or had a particular dislike for them.

Description of Study Protocol:

Recruitment

Recruitment was conducted at two primary care centers of the State University of Rio de Janeiro, Brazil.

Design

18-month randomized trial with a six-week run-in period.

Dietary Intake/Dietary Assessment Methodology

A food-frequency questionnaire (FFQ) measured compliance with the prescribed diet (energy intake, glycemic index, average glycemic load, fiber).

Intervention

- The initial phase, a six-week run-in period, consisted of two weeks of a low glycemic index diet followed by four weeks of a high glycemic index diet. Those who completed the run-in period (203 of 414 recruited) were randomized to a low glycemic index diet or a high glycemic index diet
- Dietary counseling was based on a small energy restriction (100 to 300kcal) and skipping the diet one day a week was allowed. Subjects were instructed to eat three meals and three snacks according to a six-day menu plan. Nutritional counseling was provided monthly. Both diets were designed with 26% to 28% of energy as fat. For each meal, the low glycemic index diets were designed to maintain an average difference of 40 units compared with the high glycemic index diet.

Statistical Analysis

- The intention-to-treat analysis included all subjects regardless of compliance
- Hunger and weight changes over time were analyzed for parallel groups with repeated measurements, controlling for baseline measurements
- Baseline characteristics of the two groups were compared with the T-test of chi-square test
- Hunger scales for each main meal and the sum of the three scales were compared between the groups
- Baseline food intake was compared with T-tests. Analysis for diet changes over time were compared between the groups.

Data Collection Summary:

Timing of Measurements

- FFQs were completed at the beginning of the run-in period and after three, six, 12 and 18 months of follow-up
- Weight and hunger were measured monthly
- Fasting blood samples were collected at baseline and after three, six, 12, and 18 months.

Dependent Variables

- Body weight change at 18 months
- Hunger was measured with a Likert scale from 1 to 10
- Glucose, LDL and VLDL cholesterol, insulin resistance (HOMA) and triglycerides.

Independent Variables

- Low-glycemic index diet
- High-glycemic index diet.

Control Variables

- Baseline weight
- Age
- Center
- Time
- Time x time interaction.

Description of Actual Data Sample:

- *Initial N:* 414 recruited
- *Attrition (final N):* 203 randomized who completed the run-in period
- *Mean age:* (SD)
  - Low-glycemic index group: 37.2 (5.4) years
  - High-glycemic index diet group: 37.5 (5.6) years
- *Ethnicity:* The percent of white, black, and mulatto was:
  - Low-glycemic index group: 54.5%, 19.8% and 25.7%, respectively
  - High-glycemic index group: 52.0%, 15.0% and 33.0%, respectively
- *Other relevant demographics:* Less than eight years of education:
  - 24% of the low-glycemic index group
  - 28.3% for the high-glycemic index group
- *Anthropometrics:* There were no significant (NS) differences between the two experimental groups. Those who did not complete the run-in period were less educated than those who were randomized.
- *Location:* Rio de Janeiro, Brazil.

Summary of Results:

Key Findings

- Mean weight loss (P=0.65) and reduction in hunger (P=0.74) were NS different between the groups based on a repeated measures analysis adjusted for baseline weight, age, center, time and time x time interaction. The time x time interaction was NS for either variable. Excluding dropouts did not change the results substantially. Weight change was only 0.31 kg and 0.21kg for the two groups at 18 months
- The low-glycemic index diet reduced triacylglycerol at all measurement time points until 12 months, but the only statistically significant effect of the diet was the lower VLDL-cholesterol concentration with the low-glycemic index diet (P=0.03)
- NS differences in fasting serum glucose, insulin and HOMA-insulin resistance were observed between groups at three months.

Author Conclusion:

- Long term weight changes were NS different between the high-glycemic index and low-glycemic index diet groups
- Study results do not support the hypothesis that a low-glycemic index diet enhances weight loss success
- Favorable changes in blood lipids confirm previous results.

Reviewer Comments:

- *Author-identified limitation: Losses to follow-up during the 18-month period were 38% in the low-glycemic index group and 41% in the high-glycemic index group*
- *Adherence to treatment (completing more than 10 appointments) was 61% in the low-glycemic index group and 46% in the high glycemic index group.*

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions		
1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes

Validity Questions		
1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	No
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	No
3.	**Were study groups comparable?**	Yes

3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	Yes
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	Yes
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	Yes
4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	???
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	**Was blinding used to prevent introduction of bias?**	No
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	No
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	Yes
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A

6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	Yes
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	N/A
6.6.	Were extra or unplanned treatments described?	N/A
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes
7.7.	Were the measurements conducted consistently across groups?	Yes
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**	Yes
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes

8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	Yes
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes
8.6.	Was clinical significance as well as statistical significance reported?	No
8.7.	If negative findings, was a power calculation reported to address type 2 error?	No
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**	Yes
9.1.	Is there a discussion of findings?	Yes
9.2.	Are biases and study limitations identified and discussed?	Yes
10.	**Is bias due to study's funding or sponsorship unlikely?**	Yes
10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	Yes